K111285

SEP - 9 2011

510(k) Summary
for the Salient Surgical Technologies, Inc. Aquamantys®3 Pump Generator System, Aquamantys®3 6.0 Bipolar Sealer and Aquamantys®3 8.2L Bipolar Sealer with Cutting
As Required by 21 CFR 807.87(k)

1. SPONSOR/510(K) HOLDER

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Date Prepared: May 5, 2011

2. DEVICE NAME

Proprietary Name: Aquamantys®3 Pump Generator System, which includes the Aquamantys®3 Pump Generator, Aquamantys®3 6.0 Bipolar Sealer and Aquamantys®3 8.2L Bipolar Sealer with Cutting
Common/Usual Name: Electrosurgical Generator and accessory
Classification Name: Electrosurgical cutting and coagulation device and accessories

3. PREDICATE DEVICES

- Salient Surgical (formerly TissueLink) Aquamantys Pump Generator System (includes Aquamantys Pump Generator, Aquamantys 6.0 Bipolar Sealer and Aquamantys 2.3 Bipolar Sealer), K052859
- ValleyLab ForceFX Electrosurgical Generator, K944602
- ValleyLab E2516 Electrosurgical Pencil, K813071

4. DEVICE DESCRIPTION

The Salient Surgical Aquamantys3 Pump Generator System is a general reference term used to describe use of the Salient Aquamantys3 Pump Generator together with specific, design compatible, Aquamantys3 electrosurgical instruments. The Aquamantys3 Pump Generator itself is an electrosurgical generator with, monopolar and bipolar, high-

frequency current outputs and an internal rotary peristaltic pump for delivery of saline. The Aquamantys3 Pump Generator is for use only with specific, design compatible Aquamantys3 electrosurgical instruments, for delivery of radio frequency (RF) energy for cutting of soft tissue and delivery of RF energy concurrent with saline for haemostatic sealing and coagulation of soft tissue and bone at the operative site. Currently included as part of the system in this 510(k) submission are the Aquamantys3 Pump Generator, and two hand-held, sterile, single use disposable electrosurgical devices that are compatible with the Aquamantys3 Pump Generator system. These disposable devices are the Aquamantys3 6.0 Bipolar Sealer and the Aquamantys3 8.2L Bipolar Sealer with Cutting.

The Aquamantys3 Pump Generator is a shelf-top unit consisting of a sheet metal housing and a front LCD control panel. The generator has a peristaltic pump located within the housing, which is capable of transferring saline through the disposable accessory device concurrent with the generator's provision of RF energy. The LCD control panel is touchscreen and serves as the user interface for power and saline settings. The Aquamantys3 Pump Generator has a receptacle in its front panel that provides for the disposable device connection to the generator's RF power and the peristaltic pump. The Aquamantys3 disposable device connection to the Aquamantys3 Pump Generator is configured as a cassette; the configuration is unique to the Aquamantys3 system and ensures only Aquamantys3 disposable devices with the cassette can be used with the Aquamantys3 Pump Generator. The generator accepts designated, commercially available, split-pad patient return electrode pads (neutral electrodes) for monopolar applications, and provides monitoring of the patient return circuit for safety purposes.

The Aquamantys3 6.0 Bipolar Sealer device is a modified disposable, that when connected to the Aquamantys3 Pump Generator, uses bipolar RF energy applied concurrently with saline to the operative site. The effect of RF energy applied concurrently with saline results in haemostatic sealing and coagulation of soft tissue and bone without charring; this result has been trademarked as Transcollation® technology by Salient Surgical Technologies. The proposed Aquamantys3 6.0 Bipolar Sealer shares the same handpiece, shaft and tip configuration as its predicate device, the Aquamantys 6.0 Bipolar Sealer. The proposed and predicate devices differ only in how they connect to their designated generators. The proposed Aquamantys3 device has a cassette to connect it to the Aquamantys3 Pump Generator, allowing the user to connect the device's saline tubing to the peristaltic pump at the same time as the device is connected electrically to the generator. The predicate Aquamantys disposable device, comparatively, has a standard three-prong plug for electrical connection to the Aquamantys Pump Generator and the user is required to manually feed the predicate's saline tubing into the peristaltic pump. The unique cassette connection helps prevent the

connection of Aquamantys3 devices to other, unintended or unspecified equipment.

The Aquamantys3 8.2L Bipolar Sealer with Cutting device is a disposable that, when connected to the Aquamantys3 Pump Generator, uses monopolar RF energy for cutting, and bipolar RF energy concurrent with saline for haemostatic sealing and coagulation. The device is equipped with dual electrodes at the distal tip. Saline and electrical lines exit the opposite end (proximal end) of the device's handpiece from the distal electrodes. The device's handpiece is equipped with two activation buttons; the distal yellow button activates monopolar RF energy for cutting, and the proximal blue button simultaneously activates bipolar RF energy concurrent with saline flow for haemostatic sealing and coagulation. A saline fluid delivery line is provided with the device, which includes a spike for insertion into saline bags. The electrical connection of the device to the generator, as well as the saline tubing insertion into the generator's pump, is made via a cassette interface that is part of the disposable device. The cassette assures the unique connection of Aquamantys3 disposable devices with Aquamantys3 Pump Generators.

5. INDICATION FOR USE/INTENDED USE

Aquamantys3 Generator:

The Aquamantys3 Generator is an electrosurgical generator with monopolar and bipolar RF outputs. It is intended to be used with specified disposables for delivery of RF energy for cutting of soft tissue and RF energy concurrent with saline for haemostatic sealing and coagulation of soft tissue and bone at the operative site during surgical procedures. The system is not intended for contraceptive tubal coagulation (permanent female sterilization).

Aquamantys3 6.0 Bipolar Sealer:

The Aquamantys3 Bipolar Sealer is a bipolar, single use, sterile, disposable device intended for use with the Aquamantys3 Generator. The device delivers bipolar RF energy concurrent with saline for haemostatic sealing and coagulation of soft tissue and bone. It is intended for, but not limited to, orthopaedic, spine, thoracic, and open abdominal surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Aquamantys3 8.2L Bipolar Sealer with Cutting:

The Aquamantys3 8.2L Bipolar Sealer with Cutting is a monopolar/bipolar, single use, sterile, disposable device intended for use with the Aquamantys3 Generator. The device delivers monopolar RF energy for cutting of soft tissue and bipolar RF energy concurrent with saline for haemostatic sealing and coagulation of soft tissue and bone. It is intended

for, but not limited to, orthopaedic, spine, thoracic, and open abdominal surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The Aquamantys3 Pump Generator applies the same fundamental technology as the predicate Aquamantys Pump Generator (previously cleared under K052859) in that it delivers bipolar RF energy with saline to provide haemostatic sealing and coagulation of soft tissue and bone at the operative site. The proposed generator is additionally similar to the predicate Valleylab ForceFX Generator (previously cleared under K944602) in that it delivers monopolar RF energy, in addition to bipolar RF energy, for cutting and coagulation during surgery.

The modified single-use disposable accessory device, the Aquamantys3 6.0 Bipolar Sealer, is similar to the Aquamantys 6.0 Bipolar Sealer such that both devices provide concurrent delivery of bipolar RF energy with saline. The two devices share identical handpiece, shaft and tip configurations and differ only in regard to how they connect to their respective, designated generators. The cord of the predicate Aquamantys 6.0 terminates in a standard three-prong electrical connector and has saline tubing that is manually loaded as an additional step into the peristaltic pump. The cord of the proposed Aquamantys3 6.0 terminates in a cassette that is designed to uniquely insert into the Aquamantys3 Pump Generator, providing simultaneous connection to both RF power and the peristaltic pump.

The Aquamantys3 8.2L Bipolar Sealer with Cutting applies the same fundamental scientific technology as the existing Salient Surgical Bipolar Sealers, with the addition of monopolar RF energy applied without saline, similar to a standard monopolar electrosurgical pencil, such as Valleylab's E2516 (K813071). The device's handpiece is equipped with two activation buttons; the distal yellow button activates monopolar RF energy for cutting, and the proximal blue button simultaneously activates bipolar RF energy concurrent with saline flow for haemostatic sealing and coagulation. The cord of the Aquamantys3 8.2L terminates in a cassette that is designed to uniquely insert into the Aquamantys3 Pump Generator, providing simultaneous connection to both RF power and the peristaltic pump.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The tissue effect and general performance of the Aquamantys3 Pump Generator was evaluated with each of the proposed disposable devices, the Aquamantys3 6.0 Bipolar Sealer and the Aquamantys3 8.2L Bipolar Sealer with Cutting, in in-vivo animal (porcine) studies and related verification bench tests. These verification and validation activities demonstrated the tissue effect of the Aquamantys3 system was comparable to the predicate devices for both monopolar RF for cutting and bipolar RF concurrent with saline for haemostatic sealing and coagulation (Transcollation® technology) applications. In-vivo animal study participants included surgeons, circulating nurses and Salient Surgical Technologies' personnel.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Clinical testing was not required to establish substantial equivalence between the proposed and predicate devices.

9. SUMMARY OF OTHER INFORMATION

No other testing was required to establish substantial equivalence between the proposed and predicate devices.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Testing performed, including in-vivo animal, verification and validation testing, indicates the Aquamantys3 Pump Generator, the Aquamantys3 6.0 Bipolar Sealer and the Aquamantys3 8.2L Bipolar Sealer with Cutting are substantially equivalent to the predicate devices. The proposed devices do not introduce considerations for safety and efficacy different from the considerations of their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room WO66-G609
Silver Spring, MD 20993-0002

Salient Surgical Technologies, Inc.
% Ms. Rita M. Calnan
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Portsmouth, New Hampshire 03801

SEP - 9 2011

Re: K111285
Trade/Device Name: Aquamantys®3 Pump Generator System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 29, 2011
Received: August 31, 2011

Dear Ms. Calnan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

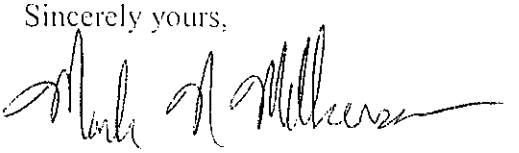
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111285

Indications for Use

510(k) Number (if known): K111285

Device Name: Aquamantys®3 Pump Generator System

Indications for Use:

The Aquamantys3 Pump Generator

The Aquamantys3 Generator is an electrosurgical generator with monopolar and bipolar RF outputs. It is intended to be used with specified disposables for delivery of RF energy for cutting of soft tissue and RF energy concurrent with saline for haemostatic sealing and coagulation of soft tissue and bone at the operative site during surgical procedures. The system is not intended for contraceptive tubal coagulation (permanent female sterilization).

Aquamantys3 6.0 Bipolar Sealer:

The Aquamantys3 Bipolar Sealer is a bipolar, single use, sterile, disposable device intended for use with the Aquamantys3 Generator. The device delivers bipolar RF energy concurrent with saline for haemostatic sealing and coagulation of soft tissue and bone. It is intended for, but not limited to, orthopaedic, spine, thoracic, and open abdominal surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Aquamantys3 8.2L Bipolar Sealer with Cutting:

The Aquamantys3 8.2L Bipolar Sealer with Cutting is a monopolar/bipolar, single use, sterile, disposable device intended for use with the Aquamantys3 Generator. The device delivers monopolar RF energy for cutting of soft tissue and bipolar RF energy concurrent with saline for haemostatic sealing and coagulation of soft tissue and bone. It is intended for, but not limited to, orthopaedic, spine, thoracic, and open abdominal surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Prescription Use x (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111285